Department of State Health Services Council Agenda Memo for State Health Services Council May 18 – 19, 2016

Agenda Item Title: Amendment to a rule concerning the Texas HIV Medication Advisory Committee.
Agenda Number: 3.e.
Recommended Council Action:
For Discussion Only
X For Discussion and Action by the Council

Background:

The Texas HIV Medication Advisory Committee (MAC) advises DSHS to develop procedures and guidelines for the Texas HIV Medication Program (THMP). The THMP helps provide medications for the treatment of HIV and its related complications for low-income Texans. The THMP is a part of the HIV/STD Prevention and Care Branch, which is located within the TB/HIV/STD/Viral Hepatitis Unit, Infectious Disease Prevention Section, Division for Disease Control and Prevention.

The MAC is charged with reviewing the THMP goals and aims, reviewing the program formulary, evaluating ongoing efforts, recommending both short-range and long-range goals and objectives for medication needs, and performing other tasks as assigned by the Health and Human Services Commission (HHSC) Executive Commissioner.

The MAC consists of 11 members appointed by the HHSC Executive Commissioner.

Summary:

The purpose of the rule amendment is to extend the date for review of committee abolishment from August 1, 2016 to August 1, 2020, based on the recommendation of the executive commissioner to continue the committee as prescribed in the current rule.

A review of DSHS advisory committees was conducted in the Fall of 2015. The MAC was a part of that review and the need for continuing the committee has been established as required in the current rule. The purpose of the proposed rule amendment will set a new expiration date for the MAC, consistent with Government Code requirements. Government Code, Section 2110.008, specifically requires that DSHS establish by rule a date for the committee to be abolished and the proposed rule reflects an expiration date that is four years from the effective date.

Key Health Measures:

TMHP monitors client demographics, drug expenditures, and utilization levels and reports that information to the MAC for their consideration as they carry out the committee tasks. The proposed rule amendment is not expected to impact the data collected or reported; however, the committee will monitor reported data as they evaluate program efforts, recommend goals and objectives for medication needs, and recommend medications for addition or deletion from the program's formulary.

Summary of Input from Stakeholder Groups:

The Health and Human Services Commission conducted a comprehensive analysis and sought stakeholder input

on the continuation of the advisory committees. The list of recommendations was posted on the HHSC and DSHS websites for three weeks in September 2015. One joint comment was received from the Texas Medical Association and the Texas Pediatric Society. They indicated support for the continuation of the committee.

The following organizations attend meetings of the MAC and will have the opportunity to review the proposed rule change: Legacy Community Health Services, Parkland Health System, Peabody Clinic, AIDS Arms Dallas, Bluitt Flowers Clinic, St. Hope Foundation, Tarrant County Health Department, FFACTS University Hospital Clinic, Valley AIDS Coalition, Thomas Street Clinic, David Powell Clinic, Travis County Health Department, Harris County Hospital District and the HIV Advocacy Work Group. These organizations serve clients who receive prescription medications through the AIDS Drug Assistance Program and the State Pharmacy Assistance Program.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item # 3.e.

Approved by Assistant Commissioner/Director:Janna ZumbrunDate: 4-13-16

Presenter: Rachel Sanor, LMSW, Program: Manager, Texas HIV

MDA

Modienties Program: Program: (512) 533-3002

MBA Medication Program

Approved by CPEA: Carolyn Bivens Date: 4-14-16

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 98. Texas HIV Medication Program
Subchapter C. Texas HIV Medication Program
Division 2. Advisory Committee
Amendment §98.121

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission (commission), on behalf of the Department of State Health Services (department), proposes an amendment to §98.121, concerning the Texas HIV Medication Advisory Committee.

BACKGROUND AND PURPOSE

The Texas HIV Medication Advisory Committee is mandated under Texas Health and Safety Code, Chapter 85, Subchapter K, and advises the Executive Commissioner and the department in the development of procedures and guidelines for the Texas HIV Medication Program, which helps provide medications for the treatment of HIV and its related complications for low-income Texans.

The proposed rule amendment would avoid abolishment of the Texas HIV Medication Advisory Committee by August 1, 2016, as prescribed in the current rule. The purpose of the rule amendment is to extend the date of Texas HIV Medication Advisory Committee abolishment from August 1, 2016, to August 1, 2020, based on the recommendation of the Executive Commissioner to continue the Texas HIV Medication Advisory Committee. A review of department advisory committees was conducted by the commission in the Fall of 2015. The need for continuing the Texas HIV Medication Advisory Committee has been established as required in the current rule.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §98.121 would change the expiration date of the Texas Medication Advisory Committee to reflect that the need for the Texas HIV Medication Advisory Committee has been established and that it should continue until August 1, 2020.

FISCAL NOTE

Ms. Imelda Garcia, Director, Infectious Disease Prevention Section, has determined that for each year of the first five years that the section will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the section as proposed.

SMALL AND MICRO-BUSINESSES IMPACT ANALYSIS

Ms. Garcia has also determined that there will be no adverse impact on small businesses or micro-businesses required to comply with the section as proposed. This was determined by interpretation of the rule that small businesses and micro-businesses will not be required to alter

their business practices in order to comply with the section. Therefore, an economic impact statement and regulatory flexibility analysis for small and micro-businesses are not required.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the section as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Garcia has also determined that for each year of the first five years the section is in effect, the public will benefit from adoption of the section. The public benefit anticipated will be the continued professional advice provided by the Texas HIV Medication Advisory Committee to the department in relation to the administration of the Texas HIV Medication Program.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendment does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Juanita Salinas, Department of State Health Services, TB/HIV/STD/Viral Hepatitis Unit, P. O. Box 149347, Mail Code 7909, Austin, Texas 78714-9347, (512) 206-5974 or by email to juanita.salinas@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rule has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendment is authorized by Texas Health and Safety Code, §85.003, which requires the department to act as lead agency and primary resource for AIDS and HIV policy; Health and Safety Code, §85.016, which allows for the adoption of rules; Health and Safety Code, §85.061, which establishes the Texas HIV Medication Program; Health and Safety Code, §85.272, which establishes the Texas HIV Medication Advisory Committee and its duties; and by Government

Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The amendment affects the Health and Safety Code, Chapters 85 and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendment)

<u>Single Underline</u> = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

Subchapter C: Texas HIV Medication Program.

Division 2: Advisory Committee.

§98.121. Texas HIV Medication Advisory Committee.

- (a) (b) (No change.)
- (c) Committee abolished. By <u>August 1, 2020,</u> [**August 1, 2016,**] the executive commissioner will initiate and complete a review of the committee to determine whether the committee should be continued, consolidated with another committee, or abolished. If the committee is not continued or consolidated, the committee shall be abolished on that date.
 - (d) (e) (No change.)